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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/017,717 | 12/14/2001 | Guy Michael Miller | 346392001500 | 5287 |

7590 11/01/2004

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| EXAMINER | |
|---|---|
| SPIVACK, PHYLLIS G | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/017,717 | MILLER ET AL. | |
| | Examiner | Art Unit | |
| | Phyllis G. Spivack | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *41,42,44-64 and 98-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41,42,44-64 and 98-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Amendment and Reply under 37 CFR 1.111 filed August 10, 2004 is acknowledged. Claims 1-40, 43 and 65-97 are/were canceled. New claims 98-104 are presented. Accordingly, claims 41, 42, 44-64 and 98-104 are now under consideration.

In the last Office Action claims 2, 11-13, 22, 31-33, 42, 53-57 and 98 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention with respect to support for the recitation "a natural metabolite".

Following the exchange of the recitation "naturally occurring" for "a natural metabolite", the rejection is withdrawn.

The rejection of claims 3, 5, 7, 8, 24-32, 39-41, and 48-50 was maintained in the last Office Action under 35 U.S.C. 112, first paragraph. It was asserted the specification, while being enabling for the administration of gamma, beta, delta tocopherols and the single metabolite gamma-CEHC to treat ischemia, does not reasonably provide enablement for any metabolite of gamma, delta or beta tocopherol in the treatment of ischemic conditions.

Applicants have limited the claimed subject matter to 50% gamma-tocopherol, a metabolite of gamma-tocopherol and gamma-CEHC, respectively, in independent claims 41, 42 and 98.

Accordingly, this rejection is withdrawn.

Claims 1-64 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-62 of co-pending application S.N. 10/020450 in the last Office Action due to overlapping subject matter.

Applicants have elected to hold in abeyance a response to this rejection.

Accordingly, the obviousness-type double patenting rejection is maintained and presently extended to include new claims 99-104.

Claims 1-64 and 98 were rejected in the last Office Action under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. It was asserted the recitations "a beta-tocopherol enriched tocopherol composition", "a beta-tocopherol metabolite enriched composition", "a delta-tocopherol enriched tocopherol composition", "a delta-tocopherol metabolite enriched composition", "a gamma-tocopherol enriched tocopherol composition" and "a gamma-tocopherol metabolite enriched composition" render the claims in which they appear indefinite. Further, while the presence of a type of tocopherol, i.e., beta, delta or gamma, in the claimed composition is clear, the language of the claims does not preclude other types of tocopherols.

Applicants have amended the claims such that only claim 41 recites "a gamma-tocopherol enriched tocopherol composition". Accordingly, claims 41, 44-52, 58-64 and 99 lack clarity in that the open language employed permits any other active ingredient including other types of tocopherols. The rejection of record under 35 U.S.C. 112, second paragraph, is maintained over claims 41, 44-52, 58-64 and presently extended to include new claim 99.

Subsequent to the cancellation of the claims, the rejection of claims 1-40 under 35 U.S.C. 102(e) as being anticipated by Wechter, W.J., U.S. 2004/0058987, is moot.

In the last Office Action claims 41-64 and 98 were rejected under 35 U.S.C. 102(e) as being anticipated by Wechter, W.J., US 2004/0058986. It was asserted Wechter teaches methods of treating and/or ameliorating the symptoms of a noncardiovascular tissue ischemic condition comprising administering a gamma-tocopherol enriched tocopherol composition or a gamma-tocopherol metabolite enriched composition. Noncardiovascular tissue ischemic conditions include spinal cord ischemia, liver ischemia, kidney ischemia, peripheral nerve damage and neuropathies.

Further, claims 1-64 and 98 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter, W.J., US 2004/0058986. It was asserted Wechter broadly claims methods of treating or preventing any ischemic condition comprising administering a composition comprising tocopherols, at least 50% of which being γ-tocopherol, as well as a metabolite (LLU-α) of gamma-tocopherol. Claimed ischemic conditions include those associated with the liver, the kidney, diabetes, thromboembolic disease, the brain, the nervous system and the eye.

In response to both rejections, Applicants argue there is no support in the specification for the claims as filed in both Wechter, W.J., US 2004/0058986, now allowed, or Wechter, W.J., US 2004/0058986, pending, for methods of treating and/or ameliorating symptoms of a non-cardiovascular tissue ischemic condition by administering a gamma-tocopherol enriched tocopherol composition comprising at least 50% gamma-tocopherol or a naturally occurring metabolite of gamma-tocopherol.

Applicants urge the claimed subject matter in the references may not benefit from the earlier filing dates.

In order to establish the validity of Applicants' arguments, the Examiner will obtain all of the Wechter applications for review. In the interim the art rejections as set forth *supra* will be maintained.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41, 44-52, 58-64 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilenko et al., Byulleten' Eksperimental'noi Biologii i Meditsiny (abstract).

Bilenko teaches the administration of alpha-tocopherol in a method of preventing lesions associated with a non-cardiovascular tissue ischemic condition. A lesion may be defined as diseased tissue. The claims differ with respect to the amount of the tocopherol. However, instant claim 41 employs open language that permits the administration of non-gamma tocopherols in the claimed method of reducing tissue death associated with non-cardiovascular tissue ischemia. The determination of an amount or type of a tocopherol in addition to gamma tocopherol is well within the purview of those skilled in the art through no more than routine experimentation. Tocopherols, other than gamma, are known in the prior art to treat non-cardiovascular ischemic conditions.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The present claims are not directed to compositions.

No claim is allowed.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 571-272-0585.

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

October 27, 2004

PHYLLIS SPIVACK
PRIMARY EXAMINER